

Remarks/Arguments

Claims 1-17 are pending in the application. Claims 1 and 16 are amended. Reconsideration and allowance are requested in light of the amendments and the following remarks.

The amendments to claims 1 and 16 clarify the elements of the claimed apparatus. Support for the amendment to claim 1 can be found, for example, in the specification at page 17, paragraph 63 and at page 20, paragraph 75. Support for the amendment to claim 16 can be found at pages 21-22 in paragraph 79. Accordingly, no new matter is added by the amendments.

Rejections under 35 U.S.C. § 102(b)

In the Office Action, the Examiner rejected claims 1-17 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,718,417 of Kittrell. Specifically, the Examiner states:

“Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Kittrell et al. U.S. Pat. No. 4,718,417. Kittrell et al., disclose a laser catheter 10 and methods of use for medical applications including diagnosis and removal of arterial vascular obstructions, the catheter comprising:

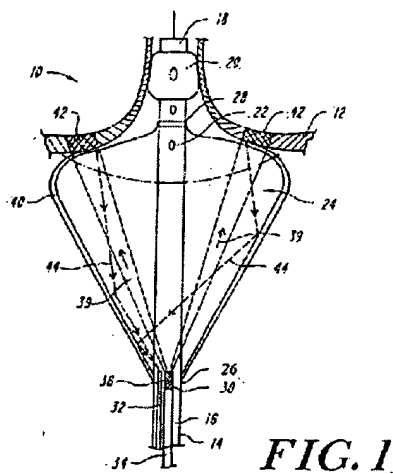
a diagnostic/illumination source 98;
a high power laser 92 for generating the ablation light;
a plurality of optical fibers for delivering both the diagnostic and ablation light beams (see Fig. 24);
a detector system including monochromator 76 and photomultiplier tube (PMT) 64; and a computer for controlling the operations of the catheter system.

Kittrell et al. (hereinafter regarded as ‘417) teach that the catheter, which is inserted into an artery, directs diagnostic and/or treatment light at a target tissue. A photodetector at the distal end of the catheter detects the backscattered fluorescent/reflected light to monitor the position of the catheter tip in relation to the target site (Col. 18, lines 4-21). The backscattered light is further analyzed to determine the characteristic of the tissues at the target site.”

Applicants respectfully disagree with the Examiner’s rejection. The amendments to claim 1 clarify the differences between Applicant’s invention and the disclosures of the Kittrell ‘417 reference.

Applicants' Invention

The present invention is an apparatus for ablating *cardiac tissue*. As shown in FIG. 1 (reproduced below), Applicants teach an apparatus that includes a catheter having a balloon member 24 adapted to contact cardiac tissue 42 upon inflation. The claimed apparatus further includes a position sensing system to ensure that the balloon is properly positioned.



Applicants' claim 1 has been amended to recite a therapeutic medical device *for ablating cardiac tissue* comprising a balloon member adapted to *contact tissue upon inflation within heart* and further adapted, upon inflation, *to expand to a size larger than a mouth of a pulmonary vein* and *define a clear pathway for transmission of ablative energy to form a lesion at least partially around the vein*, and further including a position-sensing system comprising an illuminator disposed within the balloon member which *projects light through the balloon member toward a target surface of the heart* where ablation is desired, and a collecting device also disposed within the balloon member and adapted to *receive reflected light when the balloon member is properly positioned to provide a clear pathway to the target surface of the heart for ablative energy*.

In order to determine whether the apparatus is positioned at the treatment site such that contact with the tissue occurs, Applicants measure light reflectance. For example, in one embodiment, Applicants illuminate the balloon with white light, which has several components including red and green light. Red light has a wavelength range of about 600 to about 700 nanometers (nm)

and green light has a wavelength range of about 500 to about 600 nm. When the projected light encounters blood or body fluids, most if not all green light is absorbed and hence very little green light will be reflected back toward the optical assembly which includes a reflected light collector. As a consequence, the amount of reflected green or blue light determines whether there is a clear pathway (e.g., no blood) between the apparatus and the tissue.

The Disclosure of Kittrell

Kittrell teaches a device which analyzes feedback data to assess the extent to which the plaqued tissue has been removed, i.e., comparing healthy to diseased tissue. [Col. 19, ln. 55 - Col. 20, ln. 2; Col. 20, lns. 43-65.] As shown in FIG. 4A (reproduced below), Kittrell teaches a device in which optical fibers are provided within a catheter and laser radiation is directed through the fibers for medical applications including diagnosis and removal of arterial or vascular obstructions (angiosurgery). [Col. 1, lns. 6-10.] Optical fibers 20c-20c' are mounted in a flexible inert plastic catheter having a transparent protective optical shield 12 over the distal end. [Col. 4, lns. 40-48; Col. 26, lns. 6-29.] In use, the shield is brought into contact with the plaque or other obstruction site, the intervening arterial blood is pushed away, and direct radiation for diagnosis and tissue removal is made possible. [Col. 4, lns. 48-51.]

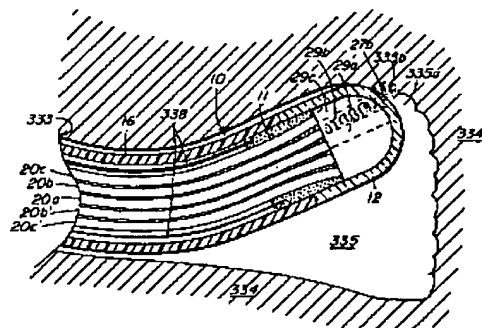


FIG. 4A

Kittrell Does not Disclose the Recitations of Applicant's Claims

Applicants' claim 1 recites a therapeutic medical device *for ablating cardiac tissue comprising a balloon member which, upon inflation, expands to a size larger than a mouth of a pulmonary vein*, an illuminator disposed within the balloon member which projects light through the balloon member toward a target surface of the heart where ablation is desired, and a collecting device dispensed within the balloon member and adapted to receive reflected light when the balloon member is properly positioned to *provide a clear pathway to the target surface of the heart for ablative energy*.

No where does Kittrell teach the features of Applicants' claim 1. As noted above, Kittrell is concerned with analyzing feedback data to determine whether the emitted light or energy is projecting onto healthy or diseased (i.e., plaqued) tissue. In contrast, Applicants analyze the reflectance data to determine the positioning of the balloon member with respect to the target tissue area (i.e., whether the balloon member has adequate contact with the target tissue area) to see if the balloon member has contacted the tissue area with sufficient force to remove any unwanted blood or body fluids. Accordingly, because Kittrell is not focused on determining whether the device is positioned against the tissue, Kittrell does not teach, and moreover, would have no need for, applicants' position sensing system.

Moreover, Kittrell has no need for (and, hence, fails to teach or suggest) a balloon member *which expands to a size larger than a mouth of a pulmonary vein*, or an illuminator *which projects light through the balloon member toward a target surface of the heart* where ablation is desired, and a collecting device dispensed within the balloon member and adapted to receive reflected light when the balloon member is properly positioned to provide a clear pathway to the target surface of the heart for ablative energy.

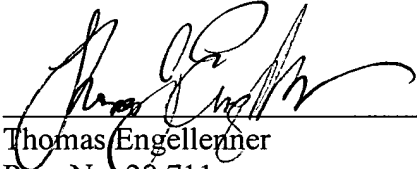
For these reasons, Kittrell fails to anticipate independent claim 1, and dependent claims 2-17 which depend therefrom. In addition, Applicants submit that each of the dependent claims recite features (e.g., intensity change monitoring, reflectance ratio measurements, partial coatings on the balloon, itself, to improve signal collection) that are not taught or suggested by Kittrell.

Conclusion

In view of the above, each of the presently pending claims (claims 1-17) in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. The Examiner is kindly requested to telephone the undersigned representative in the event that the amendments do not place this case in condition for allowance or if a telephonic interview can otherwise expedite the prosecution of this application.

Respectfully submitted,
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